Regulations

The design and installation of clean rooms must comply with various domestic and international standards.
The present chapter goes over the main regulatory texts relative to clean rooms, their installation, hygiene maintenance and fire safety.

Classification and design of clean rooms

Definition

A clean room is one in which the quality of the air is totally controlled (particulate, chemical and/or microbiological contamination) and where the temperature, moisture and pressure are controlled.

Standard ISO 146411-1

Standard ISO 14644-1 «Classification of the particulate cleanliness of clean rooms» lays down the levels of classification to be used to characterize the cleanliness of air in clean rooms.

To classify a clean room, 2 criteria must be taken in account: particulate size and the use of the premises.

The granulometric range used to classify the air cleanliness of clean rooms is between 0.1 µm *$3.9*10^{-3}$ mil* and 0.5 µm *1.9*10-2* mil inclusive.

It does not characterize the physical, chemical, radiological or viable type of particles.

Particulate cleanliness must be defined as per one or more of the following three statuses of use:

• after building : full installation with all systems engineering facilities in place and running but with no equipment, materials or products present,

• at rest : full installation with production equipment installed ready to run but with no personnel present,

• in service : installation running as per a prescribed mode with the specified personnel and working under stipulated conditions.

So, to define the cleanliness of a clean room, the designation must include :

• the classification number in the form of 'ISO class N°'

• the status of use of the premises for which air classification is desired

• the particulate sizes taken into account and the corresponding concentrations.

ISO classifications (N)	Maximum permissible concentrations (particles/m³ in air) as sizes of particles equal to or greater than the size given here under					
	0,1 µm	0,2 µm	0,3 µm	0,5 µm	1 µm	5 µm
Class ISO 1	10	2				
Class ISO 2	100	24	10	4		
Class ISO 3	1 000	237	102	35	8	
Class ISO 4	10 000	2 370	1 020	352	83	
Class ISO 5	100 000	23 700	10 200	3520	832	29
Class ISO 6	1 000 000	237 000	102 000	35 200	8 320	293
Class ISO 7				352 000	83 200	2 930
Class ISO 8				3 520 000	832 000	29 300
Class ISO 9				35 200 000	8 320 000	293 000

ABCD classes (BPF)

The ISO standard described above is today a global reference for this classification.
On the other hand, specific recommendations are applicable to certain industries such as the pharmaceutical industry. The 'Good manufacturing Practices' (GMP) define the maximum thresholds of contaminating agents and microorganisms per volume of air.

Class	Maximum authorized number of particles per m³ of a size equal to, or greater than			
	At rest		In service	
	0,5 µm	5 µm	0,5 µm	5 µm
A (work post under laminar flow)	3 500	0	3 500	0
B	35 000	0	350 000	2 000
C	350 000	2 000	3 500 000	20 000
D	3 500 000	20 000	No defined	No defined

Classification equivalents

Classification standards were previously different according to nation or activity; the table below allows you to find the equivalents of former standards under the new ISO classes :

ISO classification N° (N)	Usual class (part. 0.5 µm *1.9*10⁻² mil*/ cubic foot)	France AFNOR NF X 44.101	Good Manufacturing Practices	US Federal Standard 209 E	Number of particles >= 0,5 µm/m³ *1.9*10⁻² mil/35.31 ft³* (roughly)	Number of particles >= 0,1 µm/m³ *3.9*10⁻³ mil /35.31 ft³* (roughly)
Class ISO 1						10
Class ISO 2					4	100
Class ISO 3	1			1.5	35	1 000
Class ISO 4	10			2.5	353	10 000
Class ISO 5	100	4 000	A (at rest and in service) B (at rest)	3.5	3 530	100 000
Class ISO 6	1 000			4.5	35 300	1 000 000
Class ISO 7	10 000	400 000	B (in service) C (at rest)	5.5	353 000	
Class ISO 8	100 000	4 000 000	C (in service) D (at rest)	6.5	3 530 000	
Class ISO 9					35 000 000	

Basic principles of design

Clear basic principles for the design of clean rooms must be set out and obligatorily put into practice.

To prevent outside contamination from penetrating into the sensitive area:

• treatment of air: pressurization of room and filtration of imported air

• access control: installation of airlock and equipment decontamination system

To perform continuous extraction of contamination generated inside by the movements of operators, by machines and processing operations:

• air renewal according to a determined flow rate and fine-tuning of the room's aeraulic system: positioning of filters and air recycling units

• the mounting of vertical or horizontal laminar flow equipment at critical production locations to ensure that air displacement is completely neutralized.

To limit contamination created inside the area as much as possible (e.g.: biofilm):

- preventing condensation on interior walls by controlling temperature and humidity
- preventing crossover contamination by defining clean circuits and dirty circuits
- demanding smooth, easily cleaned surfaces.

To guarantee those parameters, coherence must be arranged and maintained between:

- the structure
- aeraulics
- logistics
- equipment required for the process.

ISO 14644-4 specifies the conditions for the building and design of units integrating clean rooms. It does not set out specific technological resources to obtain the desired classifications.
Building recommendations are suggested together with the applicable implementation and qualification conditions. Basic design and building aspects are identified via a review of relevant operating and maintenance factors.
Ref. : ASPEC guide «Clean room partition walls».

Careful : once it is installed, a clean room requires rigorous training methodology and constant checks during operations on pain of inducing a false sense of safety.

Utilisation, hygiene and safety

French standard NF U60-010
The standard sets out building rules to ensure hygiene when using food processing facilities.
This standard is backed by guides, published by the Laboratory of Studies and Research for collective catering, specific to the materials used and to their aptitude for cleaning.

Directive 93/43/EEC of 14 June 1993:
This directive sets out the principle of operator accountability within the context of respect for the general principles of hygiene. Supported by the HACCP method and the publication of a guide to best practices in hygiene, this directive lays down that facilities must eliminate all contamination («generative» and vector) by appropriate cleaning and disinfection

Order of 21 December 1993:
Automatic doors at the place of work are subject to this order. Safety devices and signalling systems must be fitted to doors to comply with this order.

Fire protection

Labour regulations R232-12 :
Dealing with fire prevention at the workplace, it is derived from decree 92.333 of 31 March 1992 and complemented by decree 94.346 of 2 May 1994.

All facilities to which workers usually have access must have exit aisles whose compulsory number and width are as follows:

	Number of exits	Total combined widths
Less than 21 persons	1	0,80 m
21 to 100 persons	1	1,50 m
101 to 300 persons	2	2,00 m
301 to 500 persons	2	2,50 m

For more than 500 persons, other conditions must be taken into account.

This article also defines exit systems for emergency evacuations as for example:
• doors, capable of being used for the evacuation of more than 50 persons, must open outwards.
• sliding doors are not considered to be regulatory exits.
• automatic powered sliding doors which, in the event of failure of the control system or for power cutouts, open the total width of the opening can be considered as regulatory exits.

Article 232-12-17 defines preventive and fire control resources:
• There must be available at least one portable pulverized water extinguisher for 200 m^2 2153 ft^2 of floor surface with at least one extinguisher per floor.
• when premises present specific fire risk, especially electrical risk, they must be equipped with extinguishers whose type and number are appropriate to the risk.
• all nonautomatic systems must be easily accessible and manipulative.

Regulations with respect to classified installations:
For certain companies, due to the type of materials used or manufacturing processes, there could be particular fire hazards. Depending on the activity, general prescriptions derived from laws and decrees and backed by prefectural orders govern safety in respect of dangerous materials and the evacuation of personnel.